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10/789,365	02/27/2004	Patrik Denoth	34097/U/S	5140
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Dorsey & Whitney LLP			VU, QUYNH-NHU HOANG	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/789,365	Applicant(s) DENOTH ET AL.
	Examiner QUYNH-NHU H. VU	Art Unit 3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

- 1) Responsive to communication(s) filed on 23 August 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-34 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Response to Amendment

Amendment and Request for Continued Examination (RCE) filed on 8/23/08 has been entered.

Claims 1-34 are present for examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No where in the Specification discloses that an implantable first fluid guiding system is replaceable, as recited in claim 1. Does Applicant mean that the first fluid guiding system 5 is releasable from the port casing 2?

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 10, 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the limitation "wherein said connecting head is fastened to said port casing by a releasable fastening engagement of said connecting element" is ambiguous. Does the "releasable fastening engagement" belong to first or second connecting element?

In claims 2-6, the limitation "the connecting elements" are ambiguous. Which is "connecting element" (first or second connecting element) that Applicant want to denote in claims 2-6?

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Furthermore, in claim 2, according to limitation "the connecting elements are elastically pressed onto each other in said fastening engagement with a pressing force" in not consistency with claim 1. The connecting element of claim 2 denotes for element 24. While, in claim 1, the first connecting element denotes for the connecting between casing 2 and the implantable port 4-4a (Fig. 2) and including element 5, 6 and 7; the second connecting element of claim 1 denotes for element 12 of the connecting device 10.

In claims 1 and 10, the limitation "...port comprising a port casing 2 which forms a first connecting element" of claim 1 is not consistency with the limitation of claim 9 " the first connecting element moulded non-flexibly on the port casing 2"

In claim 30, which is connecting element (first or second connecting element) formed of a non-flexible material?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 10-13, 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. (US 4,488,877) in view of Burbank et al. (US 6,007,516).

As best as understood, Klein discloses a port system comprising: an implantable first fluid guiding system comprising a disc-shaped supporting body 13; an external second fluid guiding system 36 with a connecting head 42 at one end; an implantable port; a port casing 12, 18 which forms a first connecting element; a connecting device 10 which comprises a second connecting element 44, 46 on an upper side of the connecting device; wherein the connecting head 42 is fastened to the port casing; wherein the connecting head 42 comprising a connecting cannula (Fig. 1).

Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., "...to a latching protrusion on an upper side facing the

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connecting head...for the second connecting element" of claim 12, a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974)

Klein does not disclose clearly the first fluid guiding system is releasable.

Burbank discloses an implantable device comprising a releasable implantable first fluid guiding system 118 (Fig. 4).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Klein with a releasable fluid guiding system, as taught by Burbank, in order to provide a convenient way by releasably or replacement fluid line between the catheter and the implantable port.

Claims 2-9, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. (US 4,488,877) in view of Burbank and further in view of Fangrow, Jr. et al. (US 5,810,792).

As best as understood, Klein in view of Burbak discloses the invention substantially as claimed. Klein does not disclose the connecting element having characters as described in claims 2-9 and 14.

Fangrow discloses the connecting element in Figs. 1-10 same as characters of claimed invention. For example: a latching protrusion 82, latching projection 68a, 68b (Figs. 7-8); connecting head 26 comprises a base body 34 or 36 (Fig. 6); or a pair of pincer 84a-b; a jowl 82

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Klein in view of Burbank with a connecting element, as taught by Fangrow, in order to provide a convenient way by releasably locking an fluid line to a receiving port.

Claims 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. (US 4,488,877) in view of Fangrow, Jr. et al. (US 5,810,792).

Klein discloses a connecting head 42 of fluid guiding system; a base body 36 and a connecting cannula of said connecting head (Fig. 1); wherein said connecting cannula fluidically connects the

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implantable port to the external fluid guiding system. Klein does not disclose a pair of pincer, a connecting jowl.

Fangrow discloses the connecting element in Figs. 1-10 same as characters of claimed invention. For example: a latching protrusion 82, latching projection 68a, 68b (Figs. 7-8); connecting head 26 comprises a base body 34 or 36 (Fig. 6); or a pair of pincer 84a-b; a jowl 82

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Klein with a connecting element, as taught by Fangrow, in order to provide a convenient way by releasably locking a fluid line to a receiving port.

Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. (US 4,488,877) in view of Burbank and further in view of Bestetti et al. (US 6,270,475).

Klein in view of Burbank discloses the invention substantially as claimed. Klein does not disclose the port casing forms a curved guide on an underside as described in claims 17-18.

Bestetti discloses an implantable device comprising a port casing 16 forms a curved guide 13, 17 on an underside (Figs. 1-2).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Klein in view of Burbank with a port casing form a curved guide, as taught by Bestetti, in order to prevent the device kinks and with more stable support.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. (US 4,488,877) in view of Svensson (US 5,098,397).

Klein discloses a port system comprising: an implantable first fluid guiding system; an external second fluid guiding system 36 with a connecting head 42 at one end; wherein the connecting head comprising a plurality of first connecting elements such as the connection to cannula below the element 36; and the other connection where is above the ridge/connecting head 42 to other fluid line (Fig. 1); implantable port 22 or 23; elements 12 and 18 are formed of port casing; a plurality of second connecting

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elements 44, 46 arranged on upper side of the connecting device 10 and the second connecting elements configured to engage with the first connecting element.

Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., "...to engage with the first connecting element" of claim 28, a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

Klein does not disclose the port casing and connecting device having of a thread surface.

As we know that, it is very common in knowledge that the thread surface having the benefit of engaging and more securing between the two components.

Meanwhile, Svensson suggests an implantable device comprising a port casing having thread surface; a connecting device 8 having thread surface configured to engage with the port casing thread surface (Figs. 1-2).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Klein with a thread surface, as taught by Svensson, in order to engage with the port casing thread surface.

Claims 29-31 rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. (US 4,488,877) in view of Svensson (US 5,098,397) and further in view of Hakansson (WO 99/34754), cited form IDS.

Klein in view of Svensson disclose the invention substantially as claimed. Klein in view of Svensson do not disclose the second connecting elements on the connecting device forms a radial protrusion to form a latching protrusion, as described in claims 29-31.

Hakansson discloses an implantable device comprising a connecting device 3 (Fig. 1); plurality of second connecting elements 14 arranged on an upper side of the connecting device (Fig. 3); wherein the second connecting elements 14 forms a radial protrusion to form a latching protrusion, said radial protrusion tapering toward upper side of the connecting device to form a latching collar (Figs. 10-11);

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Hakansson further discloses a first connecting element (lid connected with fluid line 84, see Fig. 11) forms a latching projection projecting radially inwards and having a shape that complementary to the arrangement of the connecting element latching protrusion and latching collar 11, 14, see Fig. 11.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Klein in view of Svensson with first and second connecting having radial protrusion and latch projection, as taught by Hakansson, in order to engage the first and second connecting together.

Regarding claims 31, Klein, Svensson and Hakansson discloses the claimed invention except for the connecting elements formed of a non-flexible material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a non-flexible material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. (US 4,488,877) in view of Svensson (US 5,098,397) and further in view of Fangrow, Jr. et al. (US 5,810,792).

Klein in view of Svensson disclose the invention substantially as claimed, see above rejection. Klein in view of Svensson does not disclose the connecting head having a pair of gripping element, as described in claims 32-34.

Fangrow discloses the connecting head 10 having a pair of gripping element.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Klein in view of Svensson with a connecting head, as taught by Fangrow, in order to provide a convenient way by releasably locking a fluid line to a receiving port.

Response to Arguments

Applicant's arguments with respect to claims 1-34 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763